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1	James R. Condo (#005867)			
2	Amanda C. Sheridan (#027360) SNELL & WILMER L.L.P.			
3	One Arizona Center 400 E. Van Buren, Suite 1900			
4	Phoenix, AZ 85004-2204 Telephone: (602) 382-6000			
5	jcondo@swlaw.com asheridan@swlaw.com			
6	Richard B. North, Jr. (admitted <i>pro hac vice</i>)			
7	Georgia Bar No. 545599 Matthew B. Lerner (admitted <i>pro hac vice</i>)			
8	Georgia Bar No. 446986 Elizabeth C. Helm (admitted <i>pro hac vice</i>)			
9	Georgia Bar No. 289930 NELSON MULLINS RILEY & SCARBOROUGH LLP Atlantic Station 201 17th Street, NW, Suite 1700			
10				
11	Atlanta, GA 30363 Telephone: (404) 322-6000			
12	richard.north@nelsonmullins.com matthew.lerner@nelsonmullins.com kate.helm@nelsonmullins.com			
13	Attorneys for Defendants			
14	C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.			
15				
16	IN THE UNITED STAT	ES DISTRICT COURT		
17	FOR THE DISTRI	CT OF ARIZONA		
18	IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC		
19	Litigation	DEFENDANTS' REPLY I OF MOTION TO SEAL		
20		DOCUMENTS LODGED SEAL BY PLAINTIFFS IN		
21		OF OMNIBUS STATEME FACTS IN SUPPORT OF		

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO SEAL DOCUMENTS LODGED UNDER SEAL BY PLAINTIFFS IN SUPPORT OF OMNIBUS STATEMENT OF FACTS IN SUPPORT OF RESPONSES TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT IN THE BELLWETHER CASES

(Assigned to the Honorable David G. Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") hereby submit this Reply in Motion to Seal relating to documents filed by

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Plaintiffs in support of their Omnibus Statement of Facts filed in Support of their Responses to the Motions for Summary Judgment in the Bellwether cases.

In response to the documents filed under seal, Bard reviewed the voluminous documents and addressed all of the documents in one of three ways:

- 1. Bard redacted the confidential information and filed the redacted documents. (Doc. 8443). As Plaintiffs acknowledged, this was 58 documents.
- 2. Bard sought to seal only 12 documents entirely.
- 3. After review, Bard did not seek to seal the remaining documents.¹

Plaintiffs' challenges to those redactions and the few documents Bard sought to seal are without merit. First, the sealed portions and documents meet the test of the balance necessary between the right of public access and the right to protect materials that "have traditionally been kept secret for important policy reasons." as recognized in Kamakana v. City & Cnty. of Honolulu, 447 F.3d 1172, 1179 (9th Cir. 2006) (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 597 & n. 7 (1978). The redacted and sealed information does not prevent the Court or the public from understanding the motion or the Court's ruling. For example, the Court recently ruled on Bard's motion in the Booker case and cited to testimony that was not under seal.

The documents at issue as set forth in Plaintiffs' Exhibits A and B relate to Bard's internal test methods, procedures, results and product, regulatory and marketing analysis. This is all information treated as confidential by the FDA and redacted when FOIA productions are made. Bard made these redactions consistent with those made by FDA/FOIA to protect its internal test methods and analysis. The other documents address Bard's internal product, regulatory and marketing analysis not provided to the FDA.

ARGUMENT AND CITATION OF AUTHORITY

¹ Much of Plaintiffs' argument and exhibits are focused on documents and testimony that Bard does not seek to seal. Further, Plaintiffs cite to the order in *Phillips*, but omit telling the Court that the documents at issue in *Phillips* (1) related to the filter in that case and (2) that Bard does not seek to seal them and redacted those exact types of documents so that the majority of the content is available publically.

201 17th Street NW, Suite 1700 Atlanta, GA 30363 (404) 322-6000

A. Bard has Established That Compelling Reasons Exist to Seal the Redacted Information

Plaintiffs allege in their response that Bard has failed to meet its burden to show compelling reasons to seal the redacted information because Bard relied on the Declaration of Robert Carr, but that declaration covers the very types of documents at issue. Further in the Declaration he specifically addresses the redacted confidential and trade secret information, the investment made by Bard to create the information and the procedures taken by Bard to protect it in the highly competitive medical device industry, and the harm to Bard if the information was made available to its competitors. (Doc. 7335-1). As such, Plaintiffs' argument that the motion is not supported by evidence and citation to cases in which no evidence was provided to support are motion to seal are without merit and not applicable. To the contrary, Mr. Carr addresses the types of information at issue in Bard's motion, the resources and time Bard expended to develop them and the measures Bard takes to protect them.

Further, Bard has not redacted the documents to conceal broad categories of documents or information, and instead has made limited redactions of information recognized by the FDA and the Ninth Circuit as proper for sealing. See, in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015). The redactions do not impair the public interest in understanding the Court's ruling or the judicial process. See, *Kamakana*, 447F. 3d at 1179

B. Bard has established that the Redacted and Sealed Information Contains Bard's Trade Secrets and Other Confidential Information

In their response Plaintiffs argue, without support or and evidence, that the redacted information cannot characterized as trade secret. Again, Plaintiffs ignore the Declaration of Robert Carr in which he clearly establishes that the information is trade secret. Plaintiffs offer no evidence to contradict this other than speculation.

To the contrary, a review of the redacted and sealed testing information shows that

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the tests were developed internally at Bard or through a confidential relationship with a vendor. Internal test procedures, results and analysis are trade secrets and properly sealed. See, *Jochims v. Isuzu Motors, Ltd.*, 151 F.R.D. 338, 341 (S.D. Iowa 1993) in which the court sealed trial exhibits including "internal engineering standards, confidential information regarding advertising expenditures, and test reports relating to the design and development of the Trooper. They are the kind of technical and commercial information commonly subject to confidentiality orders in cases of this kind. Depriving these documents of their confidential status would be inimical to Isuzu's competitive interests." (Emphasis added). Similarly Bard's internal testing relating to the design and analysis of its filters should be sealed.

Moreover, the other categories of redacted and sealed information at issue have long been recognized as containing information that requires sealing. See e.g., Spectrum Pharm., Inc. v. Sandoz Inc., No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014) (sealing among other "proprietary business plans" and "business practices," "actual and planned confidential communications with the FDA"); Clark v. Metro. Life Ins. Co., 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (sealing "confidential" internal business deliberations, organization, and capabilities"); Citizens Comm'n on Human Rights v. Food & Drug Admin., 1993 WL 1610471, *7 (C.D.Cal.1993) (A drug application to FDA "by definition contains trade secret information because it contains significant information about how a...drug product is formulated, chemically composed, manufactured, and quality controlled."), aff'd in part & remanded in part on other grounds, 45 F.3d 1325 (9th Cir.1995). See also, Bracco Diagnostics, Inc. v. Amersham Health Inc., CIVA 3-6025FLW, 2007 WL 2085350 (D.N.J. July 18, 2007) ("regulatory correspondence" with the FDA, "cost and profit information," "unpublished clinical studies," and "internal analyses on products which are not intended for publication or dissemination"). This is precisely the type of information Bard has redacted and seeks to seal. Plaintiffs offer no evidence to contradict the Declaration of Robert Carr that the information still has value to Bard and should be sealed.

CONCLUSION

Therefore, compelling reasons exist for protection of Bard's documents, and the Court should grant Bard's Motion to Seal for the documents at issue. Further, the redactions and sealed documents do not impair the ability of the public to understand the judicial process, Bard's motions or any ruling by the Court. As such, Bard respectfully requests that the Court enters an Order sealing the redactions in documents filed redacted in Doc. 8443 and the documents Bard seeks to seal.

This 1st day of December, 2017.

s/Elizabeth C. Helm Richard B. North, Jr. Georgia Bar No. 545599 Matthew B. Lerner Georgia Bar No. 446986 Elizabeth C. Helm Georgia Bar No. 289930 NELSON MULLINS RILEY & SCARBOROUGH, LLP **Atlantic Station** 201 17th Street, NW / Suite 1700 Atlanta, GA 30363 PH: (404) 322-6000 FX: (404) 322-6050 Kate.Helm@nelsonmullins.com

James R. Condo (#005867) Amanda Sheridan (#005867) Snell & Wilmer L.L.P. One Arizona Center 400 E. Van Buren Phoenix, AZ 85004-2204 PH: (602) 382-6000 JCondo@swlaw.com ASheridan@swlaw.com

Attorneys for Defendant C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 1, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Elizabeth C. Helm
Elizabeth C. Helm
Georgia Bar No. 289930
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000

FX: (404) 322-6050 Kate.Helm@nelsonmullins.com

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(404)		